

H. Subpart I--Program Integrity

We proposed in subpart I to specify the provisions necessary to ensure the implementation of program integrity measures and enrollee protections within the State Children's Health Insurance Program. In addition, this subpart discussed the President's *Consumer Bill of Rights and Responsibilities* as it relates to the SCHIP program. This subpart also described how the intent of the GPRA can be upheld by including program integrity performance and measures as part of the State plans.

The grievance and appeal, and privacy-related issues addressed under this Subpart of the proposed regulation are now being addressed in the new Subpart K, Applicant and Enrollee Protections.

1. Basis, scope, and applicability (§457.900).

In §457.900, we proposed under the authority of sections 2101(a) and 2107(e) of the Act to set forth fundamental program integrity requirements and options for the States. Section 2101(a) of the Act specifies that the purpose of the State Children's Health Insurance Program is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner. In addition, section 2107(e) of the Act lists specific sections of title XIX and title XI and

provides that these sections apply to States under title XXI in the same manner they apply to a State under title XIX.

The program integrity provisions contained in this subpart only apply to separate child health programs. States that implement a Medicaid expansion program are subject to the Medicaid program integrity provisions set forth in the Medicaid regulations at part 455, Program Integrity: Medicaid.

Comment: One commenter suggested that HCFA meet with the Office of the Inspector General to discuss fraud and abuse issues related to outreach to look at the legality of encouraging certain outreach strategies. The commenter noted that payment from a particular provider to a person, who the provider knows or should know would be likely to influence the individual to receive services, is prohibited.

Response: We appreciate the concern of the commenter. We routinely coordinate with the OIG regarding the review of existing and proposed regulations in accordance with the Inspector General Act, section 4(a)(2).

Comment: One commenter recommended that the entire Subpart be revised to be consistent with the requirements in the Medicare program. The commenter urged HCFA to adopt detailed requirements for both fee-for-service and managed care claims and suggested extensive revisions to the proposed rules. The commenter felt the need for flexibility did not justify State-by-State variation

with respect to the applicability or enforcement of the False Claims Act.

Response: We disagree with this comment. The Medicare program is nationally funded and administered, while Medicaid and SCHIP are jointly-funded Federal-State programs that are administered by the States within broad Federal guidelines. Therefore, it would be inappropriate and infeasible to require SCHIP and Medicaid programs to conform to fraud and abuse prevention standards of an entirely Federally funded and administered program. In addition, while we recognize the significance of the False Claims Act, standardized claims requirements are not necessary for the efficient and effective operation of the SCHIP program, or for enforcement of the False Claims Act.

Comment: One commenter felt that HCFA over-emphasized the issue of program integrity at this point in the implementation process. They suggest that the States' scarce resources and personnel would be better focused on outreach, eligibility and enrollment rather than program integrity and fraud. This commenter commended our emphasis on the need for continuity with other State programs. One commenter recommended deleting §§457.915, 457.920, 457.925, and 457.930 because the commenter felt that the proposed rule should not mandate State activities

that are subject to the administrative cap and that are not specifically required in the statute.

Response: While we appreciate the commenter's concern, we disagree with the commenter's argument that we over-emphasized program integrity too early in the implementation process. We agree that outreach, eligibility, and enrollment are all important aspects of SCHIP programs and deserve adequate resources for development and implementation. However, program integrity initiatives are also necessary now that States' programs have been established. Program integrity is essential to protecting the SCHIP program from abuse and to ensuring that the program serves those it was intended to serve, uninsured low-income children. Therefore, to protect public funds from inappropriate and unintended uses and to preserve the SCHIP program, States must have a strong fraud prevention and detection plan early in program development so that it will be in place as programs develop and mature, and serve as a viable deterrent to potential fraud and abuse.

Comment: One commenter requested clarification on the issue of limitations on provider taxes and donations as it applies to the provider contribution toward family cost-sharing requirements.

Response: The donation rules at section 1903(w) of the Act govern donations by providers or related entities directly to the

State, or to extinguish a State liability. Premiums are a liability of the recipient. When donations are given to the recipient, or to the State on behalf of the recipient, the liability of the recipient is reduced, not the liability of the State. As a reasonable safeguard, the sponsor paying the premium on behalf of the enrollee should either give the donation directly to the family, make the donation to the State tied to specific eligible individuals, or make the donation to the State which will in turn, designate the specific eligible individual(s). In the latter case, the State must assure donations are assigned to enrollees in a manner that does not favor higher income children over lower income children. In any case, the donation should not exceed the premium amount specified in the approved title XXI State plan. The section of the State plan related to cost sharing should describe the procedure for accepting such donations.

In addition, we note that providers are prohibited from giving enrollees anything of value that is likely to induce an enrollee to select a particular provider under the provisions of section 1128A(a)(5). Such conduct may subject the provider to civil monetary penalties under that section. This civil money penalty provision is administered by the Office of the Inspector General (OIG). In general, States are advised to avoid donations from providers for enrollee premiums that could unduly influence

enrollees to select a particular health plan or provider. A State that is concerned that donations for enrollee's premiums may violate these provisions may wish to seek an advisory opinion from the OIG. See 42 CFR Part 1008. The OIG will also participate in review of State plans or amendments proposing such donations.

Comment: One commenter noted that the many requirements included in this Subpart tacitly assume that the State will have a direct, contractual relationship with all SCHIP participating health plans, including premium assistance plans. However, they stated that, for premium assistance programs for group health coverage, no such contractual mechanism will exist. The employer, not the State, is the entity that contracts with the health plan; and the State is simply providing premium assistance to enable families to enroll their children in premium assistance programs, according to this commenter. Because there is no mechanism for enforcement here, the commenter stated that they are assuming that the requirements in this Subpart would not apply to employer plans. They suggested that the preamble should clarify this point. They cautioned that any attempt to apply requirements of this sort to employer plans will mean that no employer plans will ever qualify for premium assistance.

Response: While we have considered the commenter's concerns, States are responsible for the oversight of the use of

public funds to provide child health assistance through premium assistance programs just as they are responsible for oversight in other types of children's health insurance programs.

Consequently, it is not appropriate to make an exception from program integrity regulations for employer plans. In the case where the State has no direct contractual relationship with the entity providing health coverage, the State should utilize the fraud protections provided through the State insurance agency responsible for oversight of all commercial plans. For example, if State funds are provided under SCHIP to State-regulated health plans, the State insurance department anti-fraud component could conduct the State's anti-fraud oversight for its SCHIP funds. This final regulation provides flexibility to States for States to develop program integrity methods and systems that fit the needs of their particular SCHIP programs, whether or not those programs consist of premium assistance for group health plans.

2. Definitions (§457.902).

We proposed five definitions for the purpose of this subpart. We proposed that "contractor" means any individual or entity that enters into a contract, or a subcontract, to provide, arrange, or pay for services under title XXI. This definition includes, but is not limited to, managed care organizations, prepaid health plans, primary care case managers, and fee-for-service providers and insurers.

We proposed that a "managed care entity" is any entity that enters into a contract to provide services in a managed care delivery system, including, but not limited to managed care organizations, prepaid health plans, and primary care case managers. We proposed that "fee-for-service entity" means any entity that provides services on a fee-for-service basis, including health insurance services. We proposed that "State program integrity unit" means a part of an organization designated by the State (at its option) to conduct program integrity activities for separate child health programs.

Finally, we proposed to define the term "grievance" as a written communication, submitted by or on behalf of an enrollee in a child health program, expressing dissatisfaction with any aspect of a State, a managed care or fee-for-service entity, or a provider's operations, activities, or behavior that pertains to specified areas, including the availability, delivery or quality of health care services, payment for health care services and other specified areas. The grievance and appeal, and privacy-related issues addressed under this Subpart of the proposed regulation are now being addressed in the new Subpart K, Enrollee Protections.

Comment: A few commenters suggested that the definitions of "fee-for-service entity" and "contractor" raised a potential inconsistency in that the term "fee-for-service entity" does not

include "individual or entity" as "contractor" does. This suggests that individual physicians or other practitioners are exempted from the requirement at §457.950 to attest that any claims submitted for payment to be accurate, complete and truthful. The commenters noted that these practitioners are currently required to make this certification under Medicare and Medicaid.

Response: We agree with the comment and have modified the regulation text accordingly. We note again that we have created a new subpart intended to address more specifically the issues related to enrollee protections and because the term "contractor" will now apply to both this subpart and the new subpart K, we have moved the definition to §457.10.

3. State program administration (§457.910).

In §457.910 we proposed that the State child health plan must provide for methods of administration that the Secretary finds necessary for the proper and efficient operation of the separate child health program. We also proposed that the State's program must provide the safeguards necessary to ensure that eligibility will be determined appropriately in accordance with Subpart C of this regulation, and that services will be provided in a manner consistent with administrative simplification and with the provisions of Subpart D--Coverage and Benefits.

Comment: One commenter noted that the preamble language states that the Secretary wishes to give States "maximum flexibility" in the administration of their SCHIP programs. However, the commenter felt that the literal interpretation of this language translated into "methods of administration that the Secretary finds necessary," giving the Secretary too much discretion to impose methods of administration on States.

Response: We understand the commenter's concerns. The commenter is correct that the Secretary has a great deal of discretion over the requirements of the SCHIP program. We remain committed to providing States with flexibility in the administration of their SCHIP programs but, as stated in the preamble to the proposed regulation, we seek to balance this need against the Federal government's need to remain accountable for the integrity of the program. The provisions of the regulation reflect this balance and the basic framework within the regulation is necessary to ensure the integrity of SCHIP. However, this framework does not dictate to the States what methods of administration they must use to prevent and detect fraud and abuse, thereby leaving the States with significant flexibility to administer SCHIP programs.

Comment: One commenter encouraged HCFA to ensure administrative simplification, not only in the operation of the

program, but in the provision of services and with respect to providers.

Response: HCFA is committed to policy approaches that minimize the administrative burden that is placed on States in implementing their SCHIP programs in general. In addition, we are mindful of the need to strike a balance between ensuring access to SCHIP coverage, and the benefits provided under that coverage, without making it unduly burdensome for States to accomplish these goals. However, these rules address State requirements and are not intended to address State relationships with providers, which are a contractual matter between the State and providers.

4. Fraud detection and investigation (§457.915).

Section 2107(e) references sections 1903(i)(2) and 1128A of the Act, which provides a basis for certain fraud detection and investigation activities. Section 2107(e) states that these provisions apply under title XXI in the same manner as they apply to a State under title XIX. Moreover, these provisions are cited as authority in the Medicaid regulations at part 455, Subpart A - Medicaid Agency Fraud Detection and Integrity Program. In the proposed rule, we discussed in detail three possible options we considered to ensure that separate child health programs develop and implement adequate fraud detection and investigation processes and procedures. We concluded that the best approach

would be to require States to address, specifically, the Medicaid goals for fraud detection and investigation, but to allow States to design specific procedures needed to meet the requirements of §455.13. We chose neither to require States with separate child health programs to follow the same procedures for fraud detection and investigation as the Medicaid program, nor did we provide States with full latitude in designing processes and procedures. We stated that this approach balances the need for maintaining State flexibility while establishing an acceptable minimum standard that will satisfy our need for accountability in the program.

We proposed that the State must establish procedures for assuring program integrity and detecting fraudulent or abusive activity. We also proposed that the procedures must include, at a minimum, the methods and criteria for identifying suspected fraud and abuse cases as well as methods for investigating fraud and abuse cases that do not infringe on the legal rights of persons involved and afford due process of law. The State may establish an administrative agency responsible for monitoring and maintaining the integrity of the separate child health program, which is referred to in subsequent provisions of the regulation as the "State program integrity unit". We further proposed that the State must develop and implement procedures for referring suspected fraud and abuse cases to the State program integrity

unit (if such a unit is established) and to law enforcement officials. Law enforcement officials include, but are not limited to, the Department of Health and Human Services Office of Inspector General(OIG), the Department of Justice (DOJ), the Federal Bureau of Investigation (FBI), and the State Attorney General's office.

Comment: One commenter commended HCFA for recognizing that separate child health programs should not be expected to have the same fraud detection and infrastructure as required under Medicaid. However, the commenter felt that by tying goals to Medicaid fraud and abuse goals, as well as recommending the use of the State program integrity unit, HCFA was pushing the States toward Medicaid procedures without backing them up with sufficient funding levels.

Response: While we understand the commenter's concern, we specifically set out in the proposed rule a framework that attempted to provide flexibility to the States, while ensuring that States include basic, necessary protections against fraud. We are not requiring States to establish State program integrity units or to use Medicaid fraud and abuse methods or procedures to ensure the integrity of the SCHIP program. We invite States to design program integrity plans and procedures that are specific to the needs of their unique SCHIP programs within the broad framework required by the final rule. The flexibility afforded

the States in this regulation allows them to structure program integrity activities that limit the administrative burden, but still ensure the integrity of the program.

Comment: One commenter found the rules overly prescriptive and recommended the elimination of paragraph (b) that describes the "State program integrity unit" and the deletion of the requirement to refer program integrity cases to law enforcement officials in (c).

Response: The rule encourages, but does not require, States to develop or use an entity that could be called a "State program integrity unit". This concept was developed in an attempt to give the States a framework to set up an effective program integrity strategy. While not required, we believe the development of such a unit would be very beneficial to the States in designing systems to address these issues. In addition, because of Medicaid statutory provisions, States are not permitted to use existing Medicaid fraud control units (MFCUs) to conduct SCHIP program integrity activities. (While MFCUs have been given additional flexibility under the Ticket to Work Incentives Improvement Act of 1999, this flexibility only applies in cases that primarily involve Medicaid funds.) In general, States are limited to using Medicaid funds for Medicaid activities. If a State wanted to utilize the MFCU, it could only do so by hiring new staff that would be exclusively responsible

for SCHIP program integrity activities and are funded by title XXI funds. (We note that this new, separately funded "branch" of the MFCU could be called the "State program integrity unit".) Therefore, we will not eliminate §457.915(b). Finally, the inclusion of, and coordination with, appropriate Federal and State law enforcement officials as part of a State's overall fraud detection efforts, and overall program integrity efforts, is vital to the effectiveness of its program integrity activities. Therefore, we will not eliminate §457.915(c).

Comment: Several commenters noted that they appreciated the need for fraud and abuse protections, and hoped HCFA was allowing flexibility for States to utilize provider fraud detection processes of participating health plans or other State insurance department procedures. Also, these commenters hoped that States would be given sufficient time to implement these procedures.

Response: These final rules provide a structure under which States have the flexibility to use a variety of methods to create a comprehensive fraud detection strategy. While we envision that the State insurance departments may play an important role for a State in SCHIP fraud and abuse detection and investigation, we anticipate that States may want to complement those procedures already performed by the State insurance departments with procedures and goals specific to SCHIP. Specifically, fraud and abuse stemming from procedures for, or other aspects of,

participant enrollment in the separate child health program would raise distinct issues that likely fall outside of procedures established by State departments of insurance as they monitor private health plans and issuers outside of the SCHIP context. States must also address the concern that fraud and abuse may occur within a participating health plan apart from provider fraud and therefore, States must have additional procedures to detect and investigate fraud within plans. Therefore, relying on plans' processes to monitor provider fraud, while potentially useful, would not sufficiently protect against the varied types of fraud and abuse that could impact the SCHIP program in a State.

We note the commenters' concern that States need a reasonable amount of time to implement new Federal requirements. We will require that States come into conformity with new requirements within 90 days of publication of this rule, or if contract changes are necessary, the beginning of the next contract cycle. In limited cases where a new regulatory provision requires a description of procedures in the State plan, then the State must implement the procedures within the above time frame and submit the State plan amendment in compliance with §457.65(a)(2).

Comment: One commenter noted that precise, professional guidelines regarding care issues, industry-accepted standards for

fair and reasonable audits, and investigations with due process protections for providers, are essential to expand access under SCHIP.

Response: The best means of expanding access to care under SCHIP is to allow the States sufficient flexibility in designing program integrity procedures and methods as well as other aspects of their programs while maintaining a framework of Federal requirements consistent with title XXI. We encourage States to develop precise, professional guidelines as part of the design of State fraud detection and investigation methods. In addition, States should refer to industry standards in establishing audit processes as appropriate. Section 467.915(a) specifies that States must establish procedures for investigating fraud and abuse cases that do not infringe on legal rights of persons involved and afford due process of law. These requirements apply to investigations of all types of fraud and abuse under the separate child health program, including investigations that involve providers.

Comment: One commenter recommended that the language in this section be expanded to include use of procedures already in place that support these activities. In addition, they suggested revising §457.915(c) to clarify that suspected fraud and abuse cases should be referred to "appropriate" law enforcement officials as determined by State law.

Response: We have revised the regulation text at §457.915 to clarify that States must develop and implement procedures for referring suspected fraud and abuse cases to appropriate law enforcement officials, although we have not included the commenters' recommended language "as determined by State law" because referrals could be made to Federal law enforcement officials, as appropriate. We have listed certain law enforcement officials under §457.915(c) because States may wish to contact these officials with fraud and abuse information to facilitate program coordination. This is not intended to be an exhaustive list of all law enforcement officials States may contact, nor is referral to all these entities required, unless it is appropriate.

5. Accessible means to report fraud and abuse (§457.920).

We proposed that States with separate child health programs must establish, and provide access to, a mechanism of communication between the State and the public about potentially fraudulent and abusive practices by and among participating contractors, beneficiaries, and other entities. We noted in the preamble to the proposed regulation that this communication mechanism may include a toll-free telephone number, and also noted that States are free to use their discretion regarding whether to establish toll-free services for these purposes alone or to expand upon existing services. We noted that access to

toll-free service for the reporting of potentially fraudulent and abusive practices is an integral part of any sound program integrity strategy.

Comment: One commenter recommended that this provision be deleted because the rule should not mandate State activities that are subject to the administrative cap and are not specifically required by the statute.

Response: We acknowledge the commenters' point and agree that this section should be deleted. However, we have deleted this section because while we do have statutory authority to include such a provision, the provision was unnecessary and somewhat redundant.

6. Preliminary investigation (§457.925).

We proposed that if the State receives a complaint of fraud or abuse from any source, or identifies any questionable practices, the State agency must conduct a preliminary investigation or take otherwise appropriate action to determine whether there is sufficient basis to warrant a full investigation. We noted in the preamble, consistent with §457.915(b), that the State has the option of creating a "State program integrity unit" for separate child health programs that would be responsible for monitoring and maintaining the integrity of the separate child health program. We also noted that each State has flexibility to define the role played by such units but

that fraud and abuse activities relating to SCHIP must be funded with monies from the State's SCHIP allotment. Finally, while we proposed that preliminary investigations be conducted under the circumstances specified in §457.925, we remained flexible with regard to the processes and procedures that separate child health programs employ in conducting preliminary investigations and did not require or specify the procedures States must take to conduct their investigation in compliance with this requirement.

Comment: One commenter recommended that this provision be deleted because the rule should not mandate State activities that are subject to the administrative cap and are not specifically required by the statute.

Response: We disagree that this section should be deleted. As noted earlier, we maintain that these program integrity activities are necessary for the effective and efficient administration of the State plan as required in §2101(c)(2) of the statute, in addition to being based on the sound precedents set by the Medicare and Medicaid programs.

Comment: One commenter recommended that HCFA specify that States must undertake a preliminary investigation within a reasonable time not to exceed 60 days.

Response: We agree with the commenter's suggestion that a State must undertake a preliminary investigation within a certain amount of time. We have not prescribed a specific number of

days, but suggest that 60 days is indeed a reasonable amount of time to undertake a preliminary investigation. We have made the appropriate change to the regulation text.

7. Full investigation, resolution, and reporting requirements (§457.930).

We proposed that the State must establish and implement effective procedures for investigating and resolving suspected and apparent instances of fraud and abuse. We further proposed that, once the State determines that a full investigation is warranted, the State must implement certain procedures, including, but not limited to, the procedures specified at paragraphs (a) through (c) of §457.930.

We noted in the preamble to the proposed rule that States may model their approaches after procedures for fraud and abuse investigation, resolution, and reporting used by the Medicaid State agency as outlined in §§455.15, 455.16, and 455.17 of the Medicaid regulations. Medicaid funding cannot be used for fraud investigation activities in separate child health programs. MFCUs may only use Medicaid funding for fraud and abuse activities in States that provide child health assistance under a Medicaid expansion program. MFCU professional staff being paid with Medicaid dollars must be full-time employees of the Medicaid fraud agency and devote their efforts exclusively to Medicaid fraud activities. To the extent that States want to allocate

additional non-MFCU full-time staff, using SCHIP dollars, to work exclusively on fraud and abuse investigation in separate child health programs, they may do so. We noted that expenditures for this purpose would be subject to the 10 percent cap on administrative costs under section 2105(c)(2) of the Act.

Comment: One commenter suggested that a better alternative to traditional law enforcement would be to work through the provider fraud processes established by participating health plans, under which the expenditures might be considered a benefit cost rather than an administrative cost.

Response: While we intended to provide flexibility in implementing program integrity strategies, as noted in response to a comment on §457.915, States must be aware that fraud and abuse may stem from within a participating health plan or apart from providers. Therefore, States must have procedures at the State level to detect and investigate plan and issuer fraud and abuse, as well as provider fraud and abuse. Relying on plan and issuers to monitor themselves for fraud and abuse would not be in the public interest.

It is true that capitated payments made to plans in conjunction with the provision of health benefits coverage that meets the requirements of title XXI and for which the plan is at risk are not considered administrative costs. Therefore, plan activities covered by these payments are considered as

expenditures for child health assistance. However, health plan processes for the detection, investigation and resolution of fraud and abuse, and that protecting program integrity is not the only concern States must consider in designing their program integrity strategies. They must design strategies that accomplish the goals of, and comply with the requirements of, this subpart, thereby protecting against a range of potential fraud and abuse concerns, such as, but not limited to, any potentially problematic health plan activity.

Comment: Several commenters recommended that HCFA allow States the authority to enter into agreements with other investigative bodies, not strictly law enforcement officials, and not necessarily a State-established program integrity unit; rather, they recommended that States be able to contract with bodies such as health plan investigative divisions. To this aim, commenters recommended paragraph (c) be rewritten to include referring the fraud and abuse case to an appropriate investigative body as designated by the State.

Response: We agree that States should be able to structure their fraud and abuse activities in different ways; however, the inclusion of coordination with any law enforcement officials is an integral part of an effective program integrity process. We have modified the regulation text to clarify that State should be able to determine the appropriate law enforcement officials to

whom they should refer suspected fraud and abuse cases but we do not agree with the recommendation that States should not have to coordinate with any law enforcement officials. We reserve the right to review the States' program integrity procedures to ensure their compliance with the requirements and goals of title XXI and this regulation.

Comment: One commenter believed that it is unreasonable to judge States' applications or amendments based on consistency of their fraud and abuse procedures with other State programs.

Response: States are required to design and implement procedures for fraud investigation, resolution, and reporting. States are not required to file State plan amendments with HCFA in order to implement a program integrity fraud and abuse detection and investigation strategy. Therefore, HCFA will consider State's statement assuring the development and implementation of a program integrity system to be a requirement that is subject to review through HCFA's ongoing monitoring.

Comment: We received a few comments noting that requiring States with separate child health programs to set up separate structures other than Medicaid Fraud Control Units to do the same function is a waste of resources, and that requiring separate processes is burdensome and costly. One commenter recommended that States have the option to allow the MFCU to conduct SCHIP fraud investigations, assuming tracking and claiming are

conducted appropriately. Another commenter recommended deleting the provision because the rule should not mandate State activities that are subject to the administrative cap and are not specifically required by the statute.

Response: As noted above, the Medicaid statute does not permit MFCUs to conduct program integrity activities that are not related to the Medicaid program. We disagree that this section should be deleted. We maintain that program integrity activities are necessary for the effective and efficient administration of the State plan as required in section 2101(c)(2) of the statute, in addition to being based on the sound precedents set by the Medicare and Medicaid programs. While we recognize that some of these activities could be duplicative, we do not have the authority to blend the funding for fraud and abuse prevention efforts among the Medicaid and SCHIP programs.

Comment: One commenter suggested that States must have written procedures for investigating and resolving suspected and apparent instances of fraud and abuse.

Response: We agree that States should have written procedures for investigating and resolving suspected and apparent instances of fraud and abuse to ensure the effective and efficient administration of SCHIP programs. However, we are not requiring that States submit to HCFA such written procedures. We anticipate that States may continue to develop and to modify

fraud investigation and detection procedures as SCHIP programs develop. Therefore, we anticipate the methods and rules relating to program integrity will evolve as they are implemented. We wish to give the States the flexibility to improve fraud and abuse detection systems as they develop, rather than tying States to an initial written plan. However, HCFA reserves the right to review a States' program integrity procedures, and to request that they be described in writing, as part of its ongoing monitoring.

8. Sanctions and related penalties (§457.935).

Under the authority of sections 2101(a) and 2107(e) of the Act, and consistent with the requirements under Federal and State health care programs, we proposed that a State may not make payments for any item or service furnished, ordered, or prescribed under a separate child health program to any contractor who has been excluded from participating in the Medicare and Medicaid programs. We noted that this provision is necessary to implement section 1128 of the Act regarding exclusion of certain individuals and entities from participation in Medicare and State-administered health care programs. We proposed that the separate child health programs be subject to program integrity provisions set forth in the Act including: 1) section 1124 relating to disclosure of ownership and related information; 2) section 1126 relating to disclosure of

information about certain convicted individuals; 3) section 1128A relating to civil monetary penalties; and 4) section 1128B(d) relating to criminal penalties for acts involving Federal health programs. We also proposed to make separate child health programs subject to Part 455, subpart B of chapter IV of title 42 of the Code of Federal Regulations. In an effort to promote enforcement of this subsection and to provide HCFA and the Secretary with critical fraud and abuse data, we also proposed that the separate child health programs be subject to the requirements of section 1128E of the Act in the same manner as under the Medicare and Medicaid programs. In accordance with section 1128E of the Act, we proposed that the separate child health program be subject to the requirements pertaining to the reporting of final adverse actions on liability findings made against health care providers, suppliers, and practitioners. In addition, we noted in preamble that States should share such information and data with the Office of the Inspector General in an effort to promote enforcement.

We did not receive any comments on this section and will therefore implement the regulation language as proposed.

9. Procurement standards (§457.940).

Section 2101(a) of the Act requires that States provide services in an effective and efficient manner. In order to meet our obligation to ensure that States use SCHIP funds in a cost-

effective manner, we set forth provisions at proposed §457.940 regarding procurement standards. The proposed provisions did not include Federal oversight of provider payments. Rather, we proposed to require that States set rates in a manner that most efficiently utilize limited SCHIP funds.

We proposed to require that States provide HCFA with a written assurance that title XXI services will be provided in an effective and efficient manner. We also proposed that the assurance must be submitted with the initial SCHIP plan or, for States with approved SCHIP plans, with the first request to amend the SCHIP plan submitted to HCFA following the effective date of these regulations.

If States contract with entities for SCHIP services, they must provide for free and open competition, to the maximum extent possible, in the bidding of all contracts for coverage or other title XXI services in accordance with the procurement requirements of 45 CFR 74.43.

Alternatively, we proposed that States may base title XXI payment rates on public or private payment rates for comparable services. We noted in preamble that this applies to fee-for-service and capitated rates. We proposed that, if a State finds it necessary to establish higher rates than would be established using either of the above methods, it may do so if those rates are necessary to ensure sufficient provider participation or to

enroll providers who demonstrate exceptional efficiency or quality in the provision of services. For example, this method will allow States the flexibility to establish higher rates to attract providers in under-served areas or to enroll more costly specialty providers.

We also proposed that States must provide to HCFA, if requested, a description of the manner in which they develop SCHIP payment rates in accordance with the requirements of §§457.940(b)(2) and (c). The description would include an assurance that the rates were competitively bid or an explanation of the applicability of the exceptions of 45 CFR part 74, or a description of the public or private rates that were used to set the SCHIP rates, if applicable, and/or an explanation of why rates higher than those that would be established using either of these two methods are necessary. HCFA may request the description when a State first determines its rates or, for approved SCHIP plans, when it updates its rates or changes its reimbursement methodology.

Comment: We received several comments recommending with regard to §457.940(b)(1) that procurement standards in 45 CFR part 92 are more appropriate for non-entitlement programs such as SCHIP because they allow States to utilize their own procurement standards when purchasing services with Federal grant money. Flexibility will enable States to make cost-effective and quality

health plan selections. One commenter noted that flexibility to establish higher rates to ensure provider participation should be coupled with stricter enforcement.

Response: We disagree with the commenter's suggestion for changing the procurement standards applicable to SCHIP. We believe the procurement requirements of 45 CFR 74.43 are more appropriate for separate child health programs because they allow for accountability as well as State flexibility in implementation. We expect all States, not just those establishing higher rates to ensure provider participation or for other permitted purposes, to strictly enforce the procurement standards of this section.

Comment: Several commenters requested that §457.940(b)(2) be rewritten as follows: "Basing title XXI payment rates on public and/or private payment rates for comparable services for comparable populations." Several commenters felt this section should be expanded to allow States, where such comparisons cannot be made for lack of data, the ability to explain their analysis of why the rates are within acceptable parameters.

Response: We acknowledge the distinctions in rates that may need to be made based on the populations being served and have added "for comparable populations" to the regulation text as recommended. However, we disagree with the suggestion to change the regulation to allow States to explain why the payment rates

are within acceptable parameters absent sufficient supporting data. The final regulation text includes a significant amount of flexibility for States to explain how they meet the standards of §457.940(c) regarding the need for higher rates than otherwise permitted and received many comments recognizing its flexibility. We have retained the proposed language in §457.940(c) regarding acceptable bases for such higher rates because we believe rates should only be permitted to be higher under those specific circumstances.

Comment: One commenter supported the intent of the section and noted the importance of setting adequate reimbursement levels to ensure provider participation and efficient provision of services. The commenter found it problematic that about half of the States set payment rates for separate child health programs at the same levels as they do for Medicaid. The commenter encouraged HCFA to work with States to establish more reasonable rates.

Response: Each State has the authority to set reasonable rates for its SCHIP population providers. It would be inappropriate for us to dictate to the States what specific rates they should pay to participating providers, especially in those States that have a sufficient number of providers to furnish quality care to all SCHIP participants. However, in accordance with §457.495, we encourage States to set rates and generally

administer their SCHIP programs in a way that will provide access to providers and attract an adequate number of highly qualified, experienced providers with the appropriate range of specialties and expertise.

Comment: One commenter suggested that HCFA incorporate a standard that the SCHIP rates for MCEs be actuarially sound and that we should clarify the meaning of actuarial soundness in the managed care context. In addition, another commenter suggested that HCFA require States to justify or prove the methodology used to establish the payment rate.

Response: We agree with the comment that rates should be actuarially sound. Actuarially sound capitation rates means that they have been developed in accordance with generally accepted actuarial principles and practices, that are appropriate for the populations and services to be covered under the contract, and that have been certified by an actuary (or actuaries) meeting the qualification standards established by the Actuarial Standards Board. The text of the regulation at §457.940(b)(3) has been changed to reflect this and a definition is included at §457.902 - Definitions.

Comment: One commenter supported giving States maximum flexibility to take advantage of local market forces in establishing SCHIP payment rates. In this commenter's view, States should provide reimbursement for obstetric and gynecologic

services sufficient to assure that SCHIP enrollees have access equal to that of privately insured patients. This commenter also noted that providing these types of services to adolescents is often quite time consuming due to the various developmental and psycho social issues they face, and recommended that compensation for physicians should be determined accordingly.

Response: We appreciate support for the policy of giving State flexibility in their procurement and rate setting. However, it is important for States to set rates high enough to provide sufficient access to, and quality of, care for all SCHIP participants for all services. However, it is not appropriate to specify the need for enhanced payment rates for certain types of providers or services in regulation. The requirement that States provide for free and open competition in procurement or demonstrate that their rates meet the requirements of (b) or (c) should ensure that SCHIP enrollees have access to providers that are compensated appropriately within their local health care markets.

Comment: We received one comment recommending that §457.940(a) include a specific reference that States must comply with all applicable civil rights requirements in accordance with §457.130.

Response: Section 457.130, contained in subpart A (which is the subpart that sets forth many general State plan

requirements), requires States to include in their State plan an assurance that the State will administer their SCHIP program in compliance with applicable civil rights requirements. We maintain that this provision sufficiently assures this compliance.

10. Certification for contracts and proposals (§457.945).

In addition to the proposed requirements in §457.950, which specify that contractors must certify that payment data is accurate, truthful, and complete, we proposed to specify in §457.945 that entities that contract with the State under a separate child health program must also certify the accuracy, completeness, and truthfulness of information in contracts, and proposals, including information on subcontractors, and other related documents, as specified by the State.

Comment: One commenter asserted that the requirements in this section are overly burdensome for States. Because so many of the SCHIP programs utilize managed care delivery systems, the commenter noted that managed care entities are required, by virtue of executing their contracts with the States, to provide accurate, complete and truthful information. The commenter felt that a separate and distinct certification document is unnecessary.

Response: While we appreciate the administrative challenges States may face in implementing SCHIP programs, we do not believe

the requirements of this section are overly burdensome for States. The unique nature of the SCHIP program and its relationship with plans and issuers merits the inclusion in contracts of the specific certifications required by this section, and that compliance with this standard will protect against fraud and abuse in this government-funded program. The commenter may have interpreted this provision to require a separate certification document but, in fact, the required certification could be provided as part of, or together with, any of the contracts or related documents into which the State and its contractors have entered, and should entail minimal additional administrative effort.

11. Contract and payment requirements including certification of data that determines payment (§457.950).

At §457.950, we proposed that when SCHIP payments to managed care entities are based on data submitted by the MCE, the State must ensure that its contracts with MCEs require the MCE to provide enrollment information and other information required by the State. We also proposed that the State ensure that its contract requires the MCE to attest to the accuracy, completeness, and truthfulness of claims and payment data, upon penalty of perjury. As a condition of participation in the separate child health program, MCEs must provide the State with access to enrollee health claims data and payment data, as

determined by the State and in conformance with the appropriate privacy protections in the State. We also proposed that managed care contracts must include a guarantee that the MCE will not avoid costs for services, such as immunizations, covered in its contract by referring individuals to publicly supported health care resources (for example, clinics that are funded by grants provided under section 317 of the Public Health Service Act).

We proposed that when SCHIP payments are made to fee-for-service entities, the State must establish procedures to ensure and attest that information on provider claim forms is truthful, accurate, and complete. We also proposed that, as condition of participation in the State plan, fee-for-service entities must provide the State with access to enrollee health claims data and payment data, as determined necessary by the State.

Comment: One commenter agreed that agents of the State need access to payment information and that payment decisions must not be made without proper information and involvement of providers.

Response: We appreciate support for the requirements in §457.950 regarding State access to claims and payment data. As noted in the preamble, compliance with §457.950(b)(2) requires States to establish procedures to ensure and attest to the accuracy of information on provider claim forms. The State thereby must involve the provider community to the extent

necessary to comply with this requirement and the rest of §457.950, as noted in the comments.

Comment: One commenter recommended amending this section to include a requirement to comply with applicable civil rights requirements in accordance with §457.130.

Response: Section 457.130 requires States to administer the entire SCHIP program in compliance with the Civil Rights requirements noted in the title XXI statute and we maintain that this provision sufficiently assures compliance.

Comment: One commenter noted that the wording of this section is confusing. The commenter noted that because some States may make prospective monthly payments to MCEs on the first day of each month, the MCE may not have any information other than the enrollment forms from the State itself. These States may be unclear as to whether or not this section applies to their programs.

We also received a few requests that the requirement to attest to the accuracy and completeness of the data reflect that, to the extent that data is based on projections (e.g. premium rate submissions) that plans be permitted to attest to the accuracy to the best of their knowledge, information and belief. Another commenter requested deletion of the phrase "under penalty of perjury" from paragraph (a) because the requirements are already enforced through contractual language and penalties.

Also, commenters requested clarification that complete data refers to data that includes all elements required by the State.

Response: One of the fundamental tenets of program integrity is the need for certification of payment-related information. Prospective monthly payments are based on certified payment-related information despite the fact that they are developed retrospective of the services delivered. The submission of enrollment forms does not constitute payment-related information.

While we recognize that the clause "under penalty of perjury" at §457.950(a) may not have been appropriate for the entire paragraph, the Office of the Inspector General representatives indicated that it was an essential protection. Therefore, we have deleted "under penalty of perjury" from the general language of §457.950(a), but left it in §457.950(a)(2).
12. Conditions necessary to contract as a managed care entity (MCE) (§457.955).

In addition to implementing program integrity protections at the State level, we proposed under §457.955 that the State must ensure that MCEs have in place fraud and abuse detection and prevention processes. These processes would include mechanisms for the reporting of information to appropriate State and Federal agencies on any unlawful practices by subcontractors of or enrollees in MCEs. In order to maintain privacy protections for

enrollees, we proposed that the reporting of information on enrollees would be limited only to information on violations of law pertaining to actual enrollment in the plan or to, provision of, or payment for, health services. Furthermore, we proposed that the State maintains the authority and the ability to inspect, evaluate and audit MCEs, as determined necessary by the State in instances where the State determines that there is a reasonable possibility of fraudulent or abusive activity.

We noted in the preamble that States that have Medicaid expansion programs and contract with MCEs under section 1903(m) of the Act may arrange for an annual independent, external review of the quality of services (EQR) delivered by each MCE as provided for under section 1932(c)(2) of the Act. States are permitted to draw down 75 percent FFP for this activity. States with separate child health programs are encouraged to provide for EQR of each MCE under contract to provide services to SCHIP enrollees; however, expenditures for EQR would be subject to the 10 percent limit for administrative expenses under section 2105(c)(2) of the Act.

Comment: Several commenters suggested that separate SCHIP programs should not be required or encouraged (as in the preamble) to use the Medicaid external quality review of services and that there is inequity in that Medicaid expansion programs receive 75 percent FMAP for this activity while stand-alone

programs are required to stay within the 10 percent limit on administrative expenditures.

Response: While the Medicaid EQR process is a good model for States implementing separate child health programs, we are not requiring the use of this process in the regulation text, therefore States have flexibility in determining the type of quality assurance processes they utilize. Thus, States retain discretion in the use of funds for administrative expenditures and how to stay within statutory limits on such expenditures.

Comment: One commenter recommended that HCFA clarify what action by MCEs are necessary to meet the requirement that MCEs contracting under a separate child health plans have administrative and management arrangements or procedures to safeguard against fraud and abuse. The commenter asked how this requirement differ from the M+C program requirement that each M+C organization have a compliance plan. This commenter also recommended that our guidance convey that the reporting requirement in this section should only apply after the completion of a reasonable inquiry and a finding of credible evidence that a violation has occurred.

Response: We did not attempt to make the provisions of this subpart consistent with the M+C rule. As noted previously, the Medicare program is nationally-funded and administered; while

Medicaid and SCHIP are funded by a combination of State and Federal funds.

We have, however, added a provision at §457.955(b)(2) to specify that States must ensure arrangements that prohibit MCE's from conducting any unsolicited contact with a potential enrollee for the purpose of influencing an individual to enroll in the plan. This provision is added in order to prevent past abuses in which potential enrollees were influenced to join an MCE without the benefit of adequate information and education about their options in choosing an MCE and is consistent with similar provisions in Medicaid managed care, and Medicare+Choice.

Comment: We received one comment recommending that as a condition of qualification as an MCE contractor, the MCE must allow the States to inspect and audit MCEs at any time, when there is a reasonable possibility of fraud and abuse. This condition should also apply to any provider under contract to provide SCHIP services, according to this commenter.

Response: Section 457.955(d) of the NPRM states that "the State may inspect, evaluate, and audit MCE's at any time, as necessary, in instances where the State determines that there is a reasonable possibility of fraudulent and abusive activity." The regulation places the burden on the State to make sure that its contracts or arrangements with MCEs allow the State to comply with this section.

13. Reporting changes in eligibility and redetermining eligibility (§457.960).

We proposed in this section that States choosing to require that enrollees, or their representative, report changes in their circumstances during an eligibility period, the State must: (1) establish procedures to ensure that beneficiaries make timely and accurate reports of any changes in circumstances that may affect eligibility; and (2) promptly redetermine eligibility when it receives information about changes in a child's circumstances that may affect his or her eligibility.

Comment: One commenter noted that at redetermination, a child enrolled in a separate child health plan who becomes eligible for Medicaid should have a reasonable opportunity to apply and be found eligible for Medicaid without a break in coverage. The rules should specify that the child might remain enrolled in the separate child health program for up to 45 days (or longer if cause exists) while the Medicaid application is being processed in accordance with §457.360. In addition, the rules should specify that prior to any termination of SCHIP coverage, the State should screen for potential Medicaid eligibility and facilitate enrollment.

Response: We agree with the goal of providing seamless coverage to all children eligible for Medicaid or SCHIP. See subpart C for requirements regarding screening and enrollment.

These requirements apply to both eligibility determinations and redeterminations as specified at §457.350(a).

Comment: One commenter recommended that HCFA provide guidance regarding how the redetermination process should be conducted. States should not be permitted to request a re-application or require that enrollees provide information that is not needed to complete the eligibility determination. States should also be required to give the enrollee adequate time to respond to requests for additional information. States must also be required to describe in the State plan how the child will be enrolled in Medicaid without a break in coverage.

Response: We recognize the concerns of the commenter, however, the NPRM balances the need for maintaining State flexibility while establishing an acceptable standard that will satisfy our need for accountability in the program. It would be inappropriate for us to dictate methods of redetermination or a specific redetermination process that all States must use. Rather, we are concerned that States have a redetermination process because SCHIP programs are best served by leaving the specifics of the process to each State.

14. Documentation (§457.965).

To ensure the integrity of the program, we proposed to require that the State include in each applicant's record certain facts that would, if necessary, support the State's

determination of a child's eligibility. This documentation should be consistent with standard State laws and procedures.

We did not receive any comments on this section. Therefore, we are implementing this provision as set forth in the proposed rule.

15. Eligibility and income verification (proposed §457.970).

In this final regulation, proposed §457.970 has been moved from subpart I to subpart C, Eligibility to become §457.380. We have addressed comments on proposed §457.970 in subpart C.

16. Redetermination intervals in cases of suspected enrollment fraud (§457.975).

We proposed in §457.975 that if a State suspects enrollment fraud, the State may, at its own discretion, perform eligibility redeterminations with the frequency that the State considers to be in the best interest of the SCHIP program.

Comment: One commenter noted that States should carefully consider the effect of not allowing immediate reenrollment of otherwise eligible children in SCHIP. Though the suspected fraud is very unlikely to have been conducted by the child, the commenter noted that it is the child who will suffer.

Another commenter recommended deleting this section because they believed its provisions were not only unnecessary but also might easily be abused. The commenter expressed concern that

this rule could be used to justify increased scrutiny of coverage provided to racial and ethnic minorities.

Response: We appreciate this comment. We too are concerned with excluding children from coverage under SCHIP and are committed to ensure that States maintain coverage of children for as long as they are eligible and have deleted this section from the final rule.

17. Verification of enrollment and provider services received (§457.980).

We proposed in §457.980 that the State must have established systems and procedures for verifying enrollee receipt of provider services. In addition, we specified that the State must establish and maintain systems to distinguish and report enrollee claims for which the State receives enhanced FMAP payments under section 2105 of the Act. We noted that these procedures would serve as a fundamental component of other program integrity activities in this proposed rule, including the fraud detection and investigation efforts discussed under §§457.915, 457.925, and 457.930.

Comment: Several commenters noted that the provisions of this section could be difficult to implement in managed care plans and that verification may be burdensome in a capitated system. The commenters requested that we clarify that it would be acceptable if there were a provision in the contract with the

health plan to ensure provider services. One commenter expressed concern regarding external verification of provider services received in the managed care market, especially in capitation-based plans. The commenter felt that States should be able to handle this through the normal provider evaluation and review procedures used by managed care entities.

Response: It is necessary for the effective and efficient administration of any State separate child health insurance program to monitor and verify enrollee receipt of services for which providers have billed or received payment, or that providers have contracted to furnish regardless of the method of reimbursement. Therefore, the provisions of §457.980(a) apply to States using managed care plans as well as other systems of health insurance and care delivery. Plans participating in SCHIP are accountable to the State for providing services and care to SCHIP participants. States must ensure, when contracting with providers, that beneficiaries are receiving care to which they are entitled and for which States have provided funds.

Comment: We received a couple of comments noting that an error may have occurred in this section as medical providers bill the State but are not billed themselves. This section should read, "The State must establish methodologies to verify whether beneficiaries have received services for which providers have billed."

Response: We agree and have changed the text of the regulation.

18. Integrity of Professional Advice to Enrollees (§457.985).

To address our concern that enrollees have a right to make informed decisions about their medical care free from any form of financial incentive or conflict of interest involving their provider of care that could directly or indirectly affect the kinds of services or treatment offered, we proposed that States must guarantee in their contracts the protection described in proposed §457.985(e). We proposed to require that States must include in their contracts for coverage and services, provisions regarding enrollee access to information related to actions that could be subject to appeal in accordance with the "Medicare+Choice" regulation at §422.206, which discusses the protection of enrollee-provider communication and at §422.208 and §422.210(a) and (b) which discuss physician incentive limitations. We remain committed to ensuring that appropriate actions are taken to guarantee the protection of enrollee rights regarding their health care services under the Medicare, Medicaid, and SCHIP programs.

Comment: One commenter expressed its support for the requirement to provide enrollee access to information related to actions involving inappropriate arrangements that could be subject to review and appeal. One commenter noted its support

for the requirement in §457.985(e) that States prohibit gag rules and establish principles for disclosure of physician financial arrangements that could affect treatment decisions.

Response: We appreciate the support and have retained these requirements with some modification in the final rule. Section 457.985(e) has now been redesignated as §457.985(a) and (b).

Comment: One commenter believed that HCFA does not have the authority to apply the M+C physician incentive requirements to separate child health plans.

Response: We disagree with the commenter. Under Section 2101(a) of the Act, the purpose of title XXI is to provide funds to States to enable them to initiate and expand the provision of child health assistance to uninsured, low-income children in an effective and efficient manner. A State cannot provide child health assistance in an effective and efficient manner if it allows inappropriate physician incentive plans that have the effect of reducing or limiting health services.

Comment: Several commenters are concerned about the reference in proposed §457.985(e)(1) prohibiting interference with medical communications between health care professionals and patients. The proposed rule refers to M+C regulations at §422.206. The commenters would like to include only a specific reference to §422.206(a) rather than to the whole section. Section 422.206(b) includes a "conscience protection" that

appears to allow plans to refuse to include in their benefit package any counseling or referral service to which the plan asserts a moral or religious objection. Some commenters noted that there is an explicit statutory provision in the M+C portion of the Balanced Budget Act that deals with conscience-based refusals to provide services and the M+C regulatory provision parallels the statute, but there is no similar statutory requirement in SCHIP. The commenters noted that the regulation also should not reference §422.206(b) in order to preserve access to health care services and information about them. According to this commenter, a health plan that refuses to provide counseling or referral services impairs access to those services, and typically the services most at risk are reproductive health services provided to women. The commenters further argued that this provision conflicts with the CBRR goal of open communication between health care professionals and patients in all cases, without qualification or exception.

Response: We agree that the regulation should reference only §422.206(a). The remainder of §422.206 contains requirements for reporting to HCFA sanctions for Medicare+Choice organizations that are not applicable in a separate child health program. However, not all providers are required to offer all services in the SCHIP benefit packages. If a State contracts with providers that have a moral or religious objection to

providing particular services, the State retains the responsibility to assure that enrollees are informed of and have access to all services included as a part of the benefit package consistent with §457.495.

Comment: One commenter noted that the preamble to the proposed rule (p. 60928), which cross-references §422.208 of the M+C regulations, appears to apply the physician incentive requirements to separate child health programs. However, §457.995(d) and §457.985(e) appear to apply only the disclosure requirements, not the substantial financial risk requirements, to the SCHIP program. This commenter recommended that HCFA clarify this requirement.

Response: A State must guarantee compliance with all of the provisions of §422.208 (relating to limitations on physician incentive plans) and §422.210 (relating to disclosure of physician incentive plans) of this chapter as stated in §457.985.

Comment: One commenter recommended that States should be allowed to provide protections against the gag rule and physician incentives in accordance with their own State law.

Response: While we appreciate State efforts to prohibit gag rules and inappropriate physician incentive plans, it is necessary to require compliance with §422.208 and §422.210 of this chapter to ensure nationwide protection of enrollees in separate child health programs consistent with the CBRR.